K140125

APR 2 9 2014

510(k) SUMMARY
(as required by 807.92)

Regulatory Correspondent:	AJW Technology Consultants, Inc. 445 Apollo Beach Blvd. Apollo Beach, FL 33572 USA John Obrien Phone: 813-645-2855 Fax: 813-645-2856 Email: jobrien@ajwtech.com
Submitter of 510(k):	New Stetic S.A. Carrera 53 N^0 50-09 Guarne – Antioquia, Colombia Sandra Maria Montoya Email: smontoya@newstetic.com Phone: +57 4 550 00 00 Fax: +57 4 551 31 34
Date of Summary:	December 17, 2013
Trade/Proprietary Name:	New Stetic Dental Amalgam Alloy
Common/Usual Name:	Dental Amalgam, Mercury and Amalgam Alloy
Classification Name:	Class II
Product Code:	OIV
Regulation	21 CFR 872.3070

Intended Use:

New Stetic NU Alloy DP 40, NU Alloy DP, NU Alloy DP Active and Micronic Dental Amalgam Alloys are commonly used as a filling material for restoring the morphology and function of posterior teeth (cavities class I and II in molars and premolars), when these have lost their structure due to injuries such as cavities or fractures.

Device Description:

New Stetic Dental Amalgam Alloys are alloys for dental amalgam used as a filling material for oral cavities. They are made of silver, tin and copper and free of zinc. The products are packaged in different forms: pre-dosed capsules, tablets and powder.

Note: Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy – Guidance for Industry and FDA Staff was used

Predicate Device:

K940675 - Sybraloy
K820181 – Sybron/Kerr Contour
K820967 – Dispersalloy-Dispersed Phase Alloy

Substantial Equivalence:

The New Stetic Dental Amalgam Alloys are substantially equivalent in intended use and technological characteristics to the Sybron Dental Specialties, Inc "Sybraloy" under K940675, the Sybron Corp "Sybron/Kerr Contour under K820181 and the Johnson & Johnson "Dispersalloy-Dispersed Phase Alloy" under K820967. Any difference that exists between the New Stetic Amalgam and the predicate devices has no negative effect on safety or effectiveness.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Descriptive Information / Product Name			SYBRALOY	CONTOUR	DISPERSALLOY	NU ALLOY DP 40	Differences & Remarks
510(k)			K940675	K820181	K802967		
INTENDED USE			Used to provide a filling material used in restorative dentistry when mixed with mercury	Intended for use as a filling material for oral cavities.	Restorative material in dental practice.	New Stetic dental amalgam alloys are commonly used as a filling material for restoring the morphology and function of posterior teeth (cavities class I and II in molars and premolars), when these have lost their structure due to injuries such as cavities or fractures.	None. All products are intended to be used as a filling material in restorative dentistry.
CHEMICAL COMPOSITION							
Alloy	Silver	CAS 7440-22-4	39.4 – 43.7%	41%	70%	40%	The content of each component meets the requirements of ISO 24234:2004.
Alloy	Tin	CAS 7440-31-5	28.8 – 32.5%	31%	16%	31.8%	
Alloy	Copper	CAS 7440-50-8	25.8 – 29.8%	28%	13%	28.21%	
Alloy	Zinc		0%	0%	1%	0%	
Alloy-Mercury Ratio			1:0,9 – 1:1,0 (Mercury: 45 – 51%)	1:0,9 (Mercury: 47%)	1:1 (Mercury: 50%)	1:0,9 (Mercury: 47.5%)	
PHYSICAL PROPERTIES							
Compressive strength (MPa) 1h: ISO 24234 Specification: **80 MPa min** *(Results of Regular Set Tablet)*			185 MPa (26832 PSI)	124,11 MPa (18000 PSI)	127,5 MPa (18500 PSI)	87 MPa (12618 PSI) Result of Lot N°: 020713B	Although the results are not exactly the same, our tests are carried out according to ISO 24234-2004 and all products are within specifications, which ensure the suitable performance of restoration.
Compressive strength (MPa) 24h: ISO 24234 Specification: **300 MPa min** *(Results of Regular Set Tablet)*			534 MPa (77450 PSI)	441,26 MPa (64000 PSI)	427,5 MPa (62000 PSI)	364 MPa (52794 PSI) Result of Lot N°: 020713B	
Maximum Creep (%): ISO 24234 Specification: **2.0% max** *(Results of Regular Set Tablet)*			0.08%	0.10% max	0.86%	0.23% Result of Lot N°: 020713B	
Dimensional Change (%): ISO 24234 Specification: **-0.10 to +0.20 %** *(Results of Regular Set Tablet)*			0.06%	-0.1%	0.03%	-0.05%	
Particle shape			Spherical	Spherical and Lathe-cut	Spherical and Lathe-cut	Spherical and Lathe-cut	This parameter is not specified by a technical standard. It depends on the characteristics of product. This characteristic does not affect the performance of the restoration.
Trituration Time (seconds): High-speed Amalgamator, Product form: Capsules			7 – 10 seconds	8 – 10 seconds	10 – 14 seconds	11 seconds	This property depends on the characteristics of the product, however, the variations in the amalgamator (machine type, age, line voltage), even of the same brand, can modify the speed and time. It does not affect the safety and effectiveness of the product.
Working time (minutes) *Regular Set Capsules*			12 min. maximum	12 min. maximum	Not reported	8 min. maximum	This parameter is not specified by a technical standard. It depends on the characteristics of the product. This difference does not affect the performance of the restoration.

Descriptive Information / Product Name			SYBRALOY	CONTOUR	DISPERSALLOY	NU ALLOY DP	Differences & Remarks
INTENDED USE			Used to provide a filling material used in restorative dentistry when mixed with mercury	Intended for use as a filling material for oral cavities.	Restorative material in dental practice.	New Stetic dental amalgam alloys are commonly used as a filling material for restoring the morphology and function of posterior teeth (cavities class I and II in molars and premolars), when these have lost their structure due to injuries such as cavities or fractures.	None. Both products are intended to be used as a filling material in restorative dentistry.
CHEMICAL COMPOSITION							
Alloy	Silver	CAS 7440-22-4	39.4 – 43.7%	41%	70%	44.85%	The content of each component meets the requirements of ISO 24234:2004.
	Tin	CAS 7440-31-5	28.8 – 32.5%	31%	16%	31.95%	
	Copper	CAS 7440-50-8	25.8 – 29.8%	28%	13%	23.24%	
	Zinc		0%	0%	1%	0%	
Alloy-Mercury Ratio			1:0,9 – 1:1,0 (Mercury: 45 – 51%)	1:0,9 (Mercury: 47%)	1:1,0 (Mercury: 50%)	1:0,98 (Mercury: 49,6%)	
PHYSICAL PROPERTIES							
Compressive strength (MPa) 1h ISO 24234 Specification: **80 MPa min** *(Results of Regular Set Tablet)*			185 MPa (26832 PSI)	124,1 MPa (18000 PSI)	127,5 MPa (18500 PSI)	182 MPa (26397 PSI) Result of Lot N°: 010913	Although the results are not exactly the same, the tests are carried out according to ISO 24234-2004 and all products are within specifications, which ensure the suitable performance of restoration.
Compressive strength (MPa) 24h ISO 24234 Specification: **300 MPa min** *(Results of Regular Set Tablet)*			534 MPa (77450 PSI)	441,26 MPa (64000 PSI)	427,5 MPa (62000 PSI)	526 MPa (76290 PSI) Result of Lot N°: 010913	
Maximum Creep (%): ISO 24234 Specification: **2.0% max** *(Results of Regular Set Tablet)*			0.08%	0.10% max	0.86% max	0.30% Result of Lot N°: 010913	
Dimensional Change (%): ISO 24234 Specification: **-0.10 to +0.20 %** *(Results of Regular Set Tablet)*			0.06%	-0.1%	0.03%	-0.05%	
Particle shape			Spherical	Spherical and Lathe-cut	Spherical and Lathe-cut	Spherical and Lathe-cut	This parameter is not specified by a technical standard. It depends on the characteristics of product. This characteristic does not affect the performance of the restoration.
Trituration Time (seconds) High-speed Amalgamator, Product form: Capsules			7 – 10 seconds	8 – 10 seconds	10 – 14 seconds	12 – 14 seconds	This property depends on the characteristics of the product, however, the variations in the amalgamator (machine type, age, line voltage), even of the same brand, can modify the speed and time. It does not affect the safety and effectiveness of the product.
Working time (minutes) *Regular Set Capsules*			12 min. maximum	12 min. maximum	Not reported	8 min. maximum	This parameter is not specified by a technical standard. It depends on the characteristics of the product. This difference does not affect the performance of the restoration.

Descriptive Information \ Product Name			SYBRALOY	CONTOUR	DISPERSALLOY	NU ALLOY DP ACTIVE	Differences & Remarks
INTENDED USE			Used to provide a filling material used in restorative dentistry when mixed with mercury	Intended for use as a filling material for oral cavities.	Restorative material in dental practice.	New Stetic dental amalgam alloys are commonly used as a filling material for restoring the morphology and function of posterior teeth (cavities class I and II in molars and premolars), when these have lost their structure due to injuries such as cavities or fractures.	None. Both products are intended to be used as a filling material in restorative dentistry.
CHEMICAL COMPOSITION							
Alloy	Silver	CAS 7440-22-4	39.4 – 43.7%	41%	70%	44.74%	The content of each component meets the requirements of ISO 24234:2004.
	Tin	CAS 7440-31-5	28.8 – 32.5%	31%	16%	31.54%	
	Copper	CAS 7440-50-8	25.8 – 29.8%	28%	13%	23.96%	
	Zinc		0%	0%	1%	0%	
Alloy-Mercury Ratio			1:0,9 – 1:1,0 (Mercury: 45 – 51%)	1:0,9 (Mercury: 47%)	1:1,0 (Mercury: 50%)	1:0.98 (Mercury: 49.6%)	
PHYSICAL PROPERTIES							
Compressive strength (MPa) 1h ISO 24234 Specification: **80 MPa min** *(Results of Regular Set Tablet)*			185 MPa (26832 PSI)	124,11 MPa (18000 PSI)	127,5 MPa (18500 PSI)	159 MPa (23061 PSI) Result of Lot N°: 010713	Although the results are not exactly the same, the tests are carried out according to ISO 24234-2004 and all products are within specifications, which ensure the suitable performance of restoration.
Compressive strength (MPa) 24h ISO 24234 Specification: **300 MPa min** *(Results of Regular Set Tablet)*			534 MPa (77450 PSI)	441,26 MPa (64000 PSI)	427,5 MPa (62000 PSI)	500 MPa (72519 PSI) Result of Lot N°: 010713	
Maximum Creep (%): ISO 24234 Specification: **2.0% max** *(Results of Regular Set Tablet)*			0.08%	0.10% max	0.86% max	0.18% Result of Lot N°: 010713	
Dimensional Change (%): ISO 24234 Specification: **-0.10 to +0.20 %** *(Results of Regular Set Tablet)*			0.06%	-0.1%	0.03%	-0.06%	
Particle shape			Spherical	Spherical and Lathe-cut	Spherical and Lathe cut	Spherical and Lathe cut	This parameter is not specified by a technical standard. It depends on the characteristics of product. This characteristic does not affect the performance of the restoration.
Trituration Time (seconds) High-speed Amalgamator, Product form: Capsules			7 – 10 seconds	8 – 10 seconds	10 – 14 seconds	12 seconds	This property depends on the characteristics of the product, however, the variations in the amalgamator (machine type, age, line voltage), even of the same brand, can modify the speed and time. It does not affect the safety and effectiveness of the product.
Working time (minutes) *Regular Set Capsules*			12 min. maximum	12 min. maximum	Not reported	8 min. maximum	This parameter is not specified by a technical standard. It depends on the characteristics of the product. This difference does not affect the performance of the restoration.

Descriptive Information \ Product Name			SYBRALOY	CONTOUR	DISPERSALLOY	MICRONIC	Differences & Remarks
INTENDED USE			Used to provide a filling material used in restorative dentistry when mixed with mercury	Intended for use as a filling material for oral cavities.	Restorative material in dental practice.	New Stetic dental amalgam alloys are commonly used as a filling material for restoring the morphology and function of posterior teeth (cavities class I and II in molars and premolars), when these have lost their structure due to injuries such as cavities or fractures.	None. Both products are intended to be used as a filling material in restorative dentistry.
CHEMICAL COMPOSITION							
Alloy	Silver	CAS 7440-22-4	39.4 – 43.7%	41%	70%	70.14%	The content of each component meets the requirements of ISO 24234:2004.
	Tin	CAS 7440-31-5	28.8 – 32.5%	31%	16%	26.89%	
	Copper	CAS 7440-50-8	25.8 – 29.8%	28%	13%	3.86%	
	Zinc		0%	0%	1%	0%	
Alloy-Mercury Ratio			1:0,9 – 1:1,0 (Mercury: 45 – 51%)	1:0,9 (Mercury: 47%)	1:1 (Mercury: 50%)	1:1.1 – 1:1.2 (Mercury: 52.4% - 54.5%)	
PHYSICAL PROPERTIES							
Compressive strength (MPa) 1h ISO 24234 Specification: **80 MPa min** *(Results of Regular Set Tablet)*			185 MPa (26832 PSI)	124,11 MPa (18000 PSI)	127,5 MPa (18500 PSI)	183 MPa (26542 PSI) Result of Lot N°: 010913M	Although the results are not exactly the same, the tests are carried out according to ISO 24234-2004 and all products are within specifications, which ensure the suitable performance of restoration.
Compressive strength (MPa) 24h ISO 24234 Specification: **300 MPa min** *(Results of Regular Set Tablet)*			534 MPa (77450 PSI)	441,26 MPa (64000 PSI)	427,5 MPa (62000 PSI)	398 MPa (57725 PSI) Result of Lot N°: 010913M	
Maximum Creep (%): ISO 24234 Specification: **2.0% max** *(Results of Regular Set Tablet)*			0.08%	0.10% max	0.86% max	0.20% Result of Lot N°: 010913M	
Dimensional Change (%): ISO 24234 Specification: **-0.10 to +0.20 %** *(Results of Regular Set Tablet)*			0.06%	-0.1%	0.03%	-0.03%	
Particle shape			Spherical	Spherical and Lathe-cut	Spherical and Lathe cut	Lathe-cut	This parameter is not specified by a technical standard. It depends on the characteristics of the product. This difference does not affect the performance of the restoration.
Trituration Time (seconds) High-speed Amalgamator, Product form: Capsules			7 – 10 seconds	8 – 10 seconds	10 – 14 seconds	7 – 14 seconds	This property depends on the characteristics of the product, however, the variations in the amalgamator (machine type, age, line voltage), even of the same brand, can modify the speed and time. It does not affect the safety and effectiveness of the product.
Working time (minutes) *Regular Set Capsules*			12 min. maximum	12 min. maximum	Not Reported	7 min. maximum	This parameter is not specified by a technical standard. It depends on the characteristics of the product. This difference does not affect the performance of the restoration.

Sterilization and Shelf Life:

New Stetic has been producing alloys for dental amalgam since the late 80's, since that time the product has shown its clinical effectiveness and safety, as well as its stability at storage conditions. The product is produced as a combination of elemental mercury and amalgam alloy composed of silver, tin and copper, but the product is supplied separately: alloy as powder or tablet and mercury in a sachet. These components have been used by many companies around the world and for many years, and they have always shown an excellent stability during the storage time. For that reason an expiration date has not been considered necessary in order to guarantee its functionality.

Performance /Non-Clinical Testing:

Performance testing was completed in accordance to ISO 24234:2004 as recommended in the FDA Guidance Document "Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy – Guidance for Industry and FDA Staff. The testing was performed to show that the product is free from contamination.

Based on the data generated from the testing on it can be concluded that the New Stetic Dental Amalgam Alloys are substantially equivalent to the Sybron Dental Specialties, Inc Sybraloy, the Sybron Corp Contour and Johnson & Johnson Professionals, Inc Dispersalloy.

Biocompatibility

A biocompatibility summary was completed to demonstrate that the New Stetic Dental Amalgam Alloys are equivalent to the predicates. This includes supporting literature in lieu of performing biocompatibility testing. The New Stetic Dental Amalgam Alloys do not contain any new chemical components or additives nor do they use any new technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 29, 2014

New Stetic, S.A.
C/O John O'Brien
Consultant
AJW Technology Consultants, Incorporated
445 Apollo Beach Blvd.,
Apollo Beach, FL 33572

Re: K140125
Trade/Device Name: New Stetic Dental Amalgam Alloy (NU Alloy DP 40, NU Alloy DP, NU Alloy DP Active and Micronic)
Regulation Number: 21 CFR 872.3070
Regulation Name: Dental Amalgam, Mercury, and Amalgam Alloy
Regulatory Class: II
Product Codes: OIV, EJJ, ELY
Dated: January 28, 2014
Received: January 31, 2014

Dear Mr. O'Brien:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140125

Device Name: New Stetic Dental Amalgam Alloy

Indications for Use:

New Stetic NU Alloy DP 40, NU Alloy DP, NU Alloy DP Active and Micronic Dental Amalgam Alloys are commonly used as a filling material for restoring the morphology and function of posterior teeth (cavities class I and II in molars and premolars), when these have lost their structure due to injuries such as cavities or fractures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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